

**ENVIRONMENTAL PROTECTION AGENCY
OF THE STATE OF ILLINOIS**

IN THE MATTER OF:)
Commercial Sterilization Operations)
at 7775 South Quincy Street and)
830 Midway Street, Willowbrook,)
DuPage County, Illinois)
SO: 2019-)
RESPONDENT:)
Sterigenics U.S., LLC)

SEAL ORDER

This matter comes before the Acting Director of the Illinois Environmental Protection Agency, John J. Kim, pursuant to Section 34(b) of the Illinois Environmental Protection Act, 41S ILCS 5/34(b) (2018), for a Seal Order in this matter.

THE ILLINOIS ENVIRONMENTAL PROTECTION AGENCY HEREBY FINDS THAT:

1. There exist two buildings located in close proximity in the Village of Willowbrook, DuPage County, Illinois - one at 777S South Quincy Street and the other at 830 Midway Street. Both buildings house commercial sterilization operations and associated storage and transshipment activities.
2. The owner of both buildings, and the operator of the commercial sterilization operations, is Respondent, Sterigenics U.S., LLC.
3. Respondent uses ethylene oxide in its sterilization operations, and ethylene oxide is released from Respondent's buildings to the atmosphere.
4. In 1990, the United States Environmental Protection Agency listed ethylene oxide as a hazardous air pollutant under Section 112(b)(1) of the Clean Air Act, 42 U.S.C. 7412(b)(1).
5. From 1985 to 2016, the United States Environmental Protection Agency categorized ethylene oxide as "probably carcinogenic to humans."
6. In December 2016, the United States Environmental Protection Agency's Integrated Risk Information System ("IRIS") program released an "Evaluation of the Inhalation Carcinogenicity of Ethylene Oxide" ("2016 IRIS Evaluation"), which recharacterized ethylene oxide as "carcinogenic to humans" while increasing the lifetime inhalation cancer unit risk estimate for ethylene oxide about 30 times.
7. In the 2016 IRIS Evaluation, the United States Environmental Protection Agency recognized that an increased incidence and mortality of breast and lymphohematopoietic system cancers have been observed in workers at sterilization operations using ethylene oxide, and there is sufficient evidence to establish a causal relationship between ethylene oxide exposure and breast cancer in women.
8. The 2016 IRIS Evaluation noted that as a mutagenic carcinogen, ethylene oxide causes cancer by damaging DNA in cells which is then duplicated when the cells divide. Exposure to ethylene oxide increases the cancer risk because DNA damage may take place with each and every exposure that is passed on to more cells, increasing the number of mutated cells, which eventually leads to cancer in some people.

9. Respondent's operations are conducted in a densely populated, residential, industrial, commercial and governmental area with more than 19,000 people living within 1 mile of Respondent's two buildings and many more working there. Within 1 mile of Respondent's buildings, there are homes, schools, parks, government buildings and businesses.
10. The United States Environmental Protection Agency identified 7 census tracts near Respondent's operations as having cancer risk scores greater than 1 in 10,000, i.e., an additional 1 incidence of cancer per 10,000 people.
11. The United States Environmental Protection Agency collected ambient air samples at 26 discrete locations near Respondent's operations and utilized that data to model short-term and long-term ambient concentrations of ethylene oxide in the area. The United States Environmental Protection Agency provided the ambient sampling data and the results of its modeling to the United States Department of Human Services' Agency for Toxic Substances and Disease Registry ("ATSDR") and requested that the ATSDR determine: "if modeled and measured ethylene oxide concentrations represent long term conditions, would they pose a public health problem for people living and working in Willowbrook?"
12. On August 21, 2018, the ATSDR issued a Public Health Consultation Letter to the USEPA in answer to the request set forth in paragraph 11. In that Consultation Letter, the ATSDR concluded, in part, that:

It is ATSDR's conclusion that the data U.S. EPA provided suggests that residents and workers are exposed to elevated airborne EtO [ethylene oxide] concentrations from facility emissions. It is difficult to assess long-term public health implications from facility emissions because there has been no historical air monitoring in the community. ATSDR assumed that these data represent long term exposures for area residents and workers. Specifically, ATSDR concludes the following:

- 1) If measured and modeled data represent typical EtO ambient concentrations in ambient air, *on elevated cancer risk exists* (emphasis in original) for residents and off-site workers in the Willowbrook community surrounding the Sterigenics facility. These elevated cancer risks *present a public health hazard to these populations* (emphasis in original).
13. The ATSDR used the highest [then-available] residential area and commercial area sampling results (2.1 micrograms per meter³ and 9.1 micrograms per meter³, respectively) to reach its conclusion.
14. Ambient air sampling was conducted by the United States Environmental Protection Agency and the Village of Willowbrook in November and December of 2018 and January and February of 2019. The ambient data collected in November and December of 2018 consistently found outdoor ambient levels of ethylene oxide in commercial and residential areas as high or higher than the levels used by ATSDR.
15. Regulations promulgated by the United States Environmental Protection Agency under the Clean Air Act's National Emission Standards for Hazardous Air Pollutants ("NESHAP") for emission of ethylene oxide from commercial sterilization operations, 40 C.F.R. Part 63, Subpart O, well before the recognition of ethylene oxide as a human carcinogen, only required control of emissions (99% reduction of inlet emissions into the control device) from the sterilization chamber evacuation systems and the aeration rooms and did not require control of emissions from sterilization chamber back vents or from other operations at the facility (i.e., movement of sterilized material from the sterilization chamber to the aeration room and from the aeration room into storage or out on trucks for customer deliveries). So far, the emission levels from those other operations have only been crudely estimated.

16. The testing required by the federal NESHAP regulations from the sterilization process only determines the efficiency of the control equipment.
17. In the Spring of 2018, Respondent applied for and obtained a permit authorizing the connection of its back vent emissions to its existing control devices. After completing the connection, Respondent performed testing of the emissions under observation by the Illinois Environmental Protection Agency and the United States Environmental Protection Agency and demonstrated 99% control was achieved.
18. Respondent's emissions are continuing to contribute to ambient levels of ethylene oxide in the atmosphere. This impact creates an imminent and substantial endangerment to public health or welfare.
19. The Illinois Environmental Protection Agency should seal such portions of Respondent's buildings as are necessary to prevent the commencement of any new sterilization cycles using ethylene oxide until measures are in place to prevent emissions of ethylene oxide that contribute to ambient levels of ethylene oxide which present a public health hazard to residents and off-site workers in the Willowbrook community.

THEREFORE, PURSUANT TO THE AUTHORITY VESTED IN THE DIRECTOR OF THE ILLINOIS ENVIRONMENTAL PROTECTION AGENCY BY SECTION 34(b) OF THE ILLINOIS ENVIRONMENTAL PROTECTION ACT, I HEREBY ORDER THAT THE FOLLOWING PORTIONS OF RESPONDENT'S BUILDINGS ARE SEALED FORTHWITH:

All storage containers of ethylene oxide.

Persons authorized, in writing, by the Director of the Illinois Environmental Protection Agency may access the sealed portion of these properties to conduct activities within the scope of their specified authorization.

SAID PROPERTY SHALL REMAIN SEALED UNTIL SUCH TIME AS THIS SEAL ORDER HAS BEEN RESCINDED BY THE ILLINOIS ENVIRONMENTAL PROTECTION AGENCY.

It is a Class A misdemeanor to break any seal or operate any sealed facility until the seal is removed according to law.

Signed:



John J. Kim, Acting Director

Environmental Protection Agency of
the State of Illinois

Date: 2-15-19